

implied that it might be taken as frequently as desired with safety; (2) in that it was for use by man and contained a chemical derivative of barbituric acid, phenobarbital, which derivative has been found by the Federal Security Administrator, after investigation, to be, and by regulations designated as, habit-forming, and (a) its label failed to bear the statement: "Warning—May be habit forming" in juxtaposition with the name and quantity or proportion of such derivative of barbituric acid, and (b) its label failed to bear, as such regulations specify, the name and quantity or proportion of phenobarbital and the statement: "Warning—May be habit forming," immediately following, without intervening written, printed, or graphic matter, the name by which such drug was titled.

On August 17, 1943, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

905. Misbranding of Utra-Jel. U. S. v. 5 Boxes of Utra-Jel. Decree of condemnation and destruction. (F. D. C. No. 6621. Sample No. 54631-E.)

This product, in addition to being dangerous to health when used as directed, bore statements on its labeling which created the false and misleading impression that it was a safe and effective treatment for the conditions indicated below.

On December 29, 1941, the United States attorney for the Eastern District of Pennsylvania filed a libel against 5 boxes, each containing 4 tubes, of Utra-Jel at Philadelphia, Pa., alleging that the article had been shipped on or about November 29, 1941, from Chicago, Ill., by Pynosol Laboratories, Inc.; and charging that it was misbranded.

Analysis showed that the article consisted essentially of a castor oil soap, water, pine oil, and combined iodine.

The article was alleged to be misbranded in that the following statements appearing on its labeling created the false and misleading impression that it was a safe and effective treatment for the conditions hereafter quoted, whereas it was not a safe and effective treatment, but was a dangerous drug: (Tube) "Indicated As An Aid—In Treatment of Minor Infections Of The Cervix And Cervical Canal. As a Uterine Evacuant," (carton) "Indicated as an aid . . . in the treatment of minor infections of the cervix and cervical canal. As a uterine evacuant," (circular) "Cervical Infections And Cervical Erosions (minor) * * * Infections Of The Cervical Canal (Minor) * * * Cystic Cervix * * * As A Uterine Evacuant."

It was alleged to be misbranded further in that it was dangerous to health when used in the dosage or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof, as follows: (Circular) "take cotton applicator saturated with UTRAJEL and apply to infected parts. If cervix is extensively eroded, apply 1 cc. to 3 cc. on a wool tampon and place against cervix and leave in place about 12 hours. * * * In addition to the same procedure as outlined in the above paragraph, saturate a small gauze packing with UTRAJEL and insert into the cervical canal, leaving a loose end so that the patient may remove in about 12 hours. * * * Prepare field, gently insert sterilized applicator into the external os and pass it carefully along the canal and into the mouth of the uterus remembering the position of the uterus as determined by previous bimanual examination. DOSAGE: 5 cc. to 12 cc. the first month, 15 cc. the second month, 20 cc. to 30 cc. the third month and over. The dosages suggested may be varied slightly depending upon the individual case. In all cases treatment should be administered slowly to eliminate as much the possibility of shock * * *."

On November 10, 1942, an answer to the libel having been filed by Pynosol Laboratories, Inc., and later withdrawn, judgment of condemnation was entered and the product was ordered destroyed.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS²

906. Action to enjoin and restrain interstate shipments of a drug designated as Korjena. U. S. v. Jerome V. Gladke (Korjena Medicine Co.). Permanent injunction granted. (Inj. No. 51.)

On March 1, 1943, the United States attorney for the Western District of New York filed a complaint for an injunction against Jerome V. Gladke, trading as the

² See also No. 902.